

REMARKS

Claim 1 has been amended to recite "consisting essentially of" language. Claim 11 has been added based on the disclosure at, e.g., page 3 in the specification and reciting the composition of claim 1. Claims 12-19 have been added corresponding to claims 3-10 except for claiming a method and depending on a method claim.

Entry of the above amendment is respectfully requested.

Obviousness Rejection

The Advisory Action indicates that claims 1 and 3-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. and Ogata et al.

The Examiner states that the request for reconsideration has been considered but does not overcome the rejection because of the reasons listed on the Continuation Sheet attached to the Advisory Action. Applicants' comments on various issues raised by the Examiner are as follows.

(1) With respect to the argument that the scope of the compound of the instant invention is quite different from Inoue, the Examiner indicates that this is not persuasive because Inoue teaches the elected compound.

In response, Applicants wish to clarify that the argument being made is that the present invention is a selection invention from the overall disclosure of Inoue and that the particular invention claimed in the present application provides unexpected results, as discussed further below.

(2) In regard to the argument that an inventive feature of the instant application is the deterioration of solubility by the presence of NaCl and that the deterioration is not a function of

pH of the aqueous solution but the structure of the terminal group of the compound, according to Test Example 1, the Examiner indicates that this is not persuasive because no such solubility properties are required by the instant claims.

In response, Applicants submit initially that an advantageous property of Applicants' invention can be the subject of an argument for patentability without being recited in the claims. Indeed, as indicated in MPEP 716.02(f), evidence and arguments directed to advantages not disclosed in the specification cannot be disregarded. *In re Chu*, 66 F.3d 292, 298-99, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995).

Further, Applicants have added claims reciting an advantageous property of the present invention, namely, claims reciting increasing solubility of the thiazole derivative of formula (I).

(3) Regarding the argument that since Inoue suggests the use of NaCl as an isotonic agent in addition to glucose the art would not be motivated to choose an additive from the group of polyol, sugar alcohol, boric acid and a salt of boric acid, the Examiner indicates that this is not persuasive because the instant claims do not exclude NaCl, the teaching of glucose, a sugar, certainly would lead to substitution with other related compounds such as a polyol or a sugar alcohol, and the rejection is not based on Inoue alone, but on the combination of references.

In response, Applicants have amended claim 1 to change "A composition comprising" to "A composition consisting essentially of", since the "consisting essentially of" language excludes components (such as NaCl) that would have a material effect on the basic and novel characteristics of the present invention (such as solubility, as shown in Table 1 in the present application). In view of the amendment, Applicants wish to emphasize that the claimed

invention provides unexpectedly superior results (e.g., with respect to solubility, as shown in the experimental evidence presented in the specification).

(4) As to the argument that other ionic components also lead to decreased solubility and the recited additives do not comprise any ionic component, the Examiner indicates that this is not persuasive because ionic compounds are not excluded from the instant claims by the open language “comprising”.

In response, Applicants submit that as noted above, claim 1 has been amended to change “comprising” to “consisting essentially of”. Accordingly, Applicants submit that such ionic compounds are excluded because they would have a material effect on the basic and novel characteristics of the invention, as can be seen from Table 2 in the present application.

(5) Further, the Examiner indicates that he is not persuaded by the argument that the structure of the compound disclosed in Ogata, which has diminished solubility in water at pH 3-6.5, is completely different from that of the compound of instant claim 1, which is always decreased in solubility, irrespective of the pH, such that one would not come up with the idea to apply the isotonic agents for quinolone carboxylic acid with the compound of instant formula (I). In this regard, the Examiner indicates that the fact that Ogata teaches glycerin, mannitol, boric acid and glucose as isotonic agents would lead to their substitution in the Inoue compositions, since according to MPEP 2144.06 (II), it would have been obvious to substitute an art recognized equivalent known for the same purpose (in the instant case as isotonic agents).

In response, Applicants submit that their invention (particularly with the claims now reciting “consisting essentially of” language) provides unexpected results, including with respect

to solubility and precipitation as shown in Tables 1 and 2 in the present application, thereby rebutting any *prima facie* case of obviousness.

(6) As to the argument that since Inoue does not even suggest the object of the present invention, i.e., preparing a clear and stable aqueous composition with the specific compound of the instant invention whose solubility in water will be decreased in the presence of an ionic component, the Examiner indicates that this is not persuasive, because such language does not appear in the claims, nor are any concentrations recited in the claims.

In response, Applicants submit that as discussed above, language directed to advantages does not need to be recited in the claims (see MPEP 716.02(f) and the *In re Chu* case cited therein). Further, Applicants have added claims directed to an advantage of the present invention, as noted above.

Thus, Applicants submit that the present invention is not obvious, and withdrawal of this rejection is respectfully requested.

PTO/SB/08 Form

Applicants note that the Examiner has attached a PTO/SB/08 form to the Advisory Action in which he has again lined through the cited reference, this time because the reference is not in English. However, Applicants submit that the Examiner's position is improper, because a concise explanation of the relevance of the foreign language document was provided (see page 2 of the IDS filed June 20, 2008 referring to the English translation of the foreign Office Action submitted with the IDS, as well as MPEP 609.04(a)III, which states that "the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of

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the search report or action which indicates the degree of relevance found by the foreign office"). Accordingly, Applicants respectfully request that the Examiner consider the reference at issue (CN 1761655 A) and return an initialed PTO/SB/08 form with the next communication from the PTO. Applicants note that the reference at issue corresponds to WO 2004/067521 A1 cited by the Examiner in the rejection of the present claims, so the Examiner has in essence already considered the reference at issue.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Bruce E. Kramer
Registration No. 33,725

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
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CUSTOMER NUMBER

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